

## Message Text

UNCLASSIFIED

PAGE 01 BERN 02717 070846Z  
ACTION HEW-06

INFO OCT-01 EUR-12 ISO-00 OES-07 MED-03 /029 W  
-----092879 070912Z /20

P 070755Z JUN 78

FM AMEMBASSY BERN

TO SECSTATE WASHDC PRIORITY 6393

INFO AMEMBASSY VIENNA PRIORITY

AMEMBASSY COPENHAGEN PRIORITY

AMEMBASSY PARIS PRIORITY

AMEMBASSY BONN PRIORITY

AMEMBASSY LONDON PRIORITY

AMEMBASSY THE HAGUE PRIORITY

AMEMBASSY OSLO PRIORITY

AMEMBASSY MADRID PRIORITY

AMEMBASSY ROME PRIORITY

AMEMBASSY STOCKHOLM PRIORITY

AMCONSUL ZURICH POUCH

UNCLAS BERN 2717

39 11652: N/A

TAGS: OGEN, EIND, TBIO, XG

SUBJ: FDA ADVISORY - DEFECTIVE INTRA-AORTIC BALLOON PUMPS  
(RECALL T-098-8)

REF: STATE 138793 NOTAL

1. EMBASSY HAS CONTACTED SWISS CONSIGNEES LISTED  
IN REFTEL AS WELL AS AMERICAN COMPANY'S AGENT, KONTRON  
AG OF ZURICH. KONTRON INFORMED US THAT ONLY ONE MODLE  
10 AVCO BALLOON PUMP IN OPERATION IN SWITZERLAND (KAN-  
TONSSPITAL ZURICH) AND THAT UNIT RETROFITTED BEGINNING  
MAY. CENTRE HOSPITALIER UNIVERSITAIRE VAUDOIS IN  
LAUSANNE, ALSO CITED IN REFTEL, USED MODEL 7.

2. JONTRON ACTS AS EXCLUSIVE AGENT FOR AVCO ALSO IN  
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AUSTRIA, BELGIUM, DENMARK, FRANCE, W. GERMANY, BRITAIN,  
ITALY, HOLLAND, NORWAY, SPAIN, AND SWEDEN. WHEN KONTRON  
ZURICH WAS INFORMED APRIL 12 OF MODEL 10'S MALFUNCTIONING,  
SWISS FIRM IMMEDIATELY ALERTED ITS SUBAGENTS IN AFORE-  
MENTIONED COUNTRIES. DURING MAY REGROFIT COMPONENTS  
WERE SUPPLIED WHERE APPROPRIATE.

3. KONTRON PERPLEXED BY LIST OF COUNTRIES AND NAMES OF CLINICS SUBMITTED BY FDA. SWISS FIRM CLAIMS NO NUMBER MODEL 10S SUPPLIED TO BELGIUM OR SWEDEN AT ALL AND NONE TO A NUMBER OF INDIVIDUAL HOSPITALS LISTED. OTHERS, WHICH DID RECEIVE DEFECTIVE UNITS, WERE OMITTED FROM LIST. CASE IN POINT IS MEDIZINISCHE KLINIK IN GOETTINGEN, W. GERMANY. WARNER

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NNN

## Message Attributes

**Automatic Decaptioning:** X  
**Capture Date:** 01 jan 1994  
**Channel Indicators:** n/a  
**Current Classification:** UNCLASSIFIED  
**Concepts:** PUMPS, FOOD & DRUG REGULATIONS  
**Control Number:** n/a  
**Copy:** SINGLE  
**Draft Date:** 07 jun 1978  
**Decaption Date:** 01 jan 1960  
**Decaption Note:**  
**Disposition Action:** n/a  
**Disposition Approved on Date:**  
**Disposition Case Number:** n/a  
**Disposition Comment:**  
**Disposition Date:** 01 jan 1960  
**Disposition Event:**  
**Disposition History:** n/a  
**Disposition Reason:**  
**Disposition Remarks:**  
**Document Number:** 1978BERN02717  
**Document Source:** CORE  
**Document Unique ID:** 00  
**Drafter:** n/a  
**Enclosure:** n/a  
**Executive Order:** N/A  
**Errors:** N/A  
**Expiration:**  
**Film Number:** D780237-0669  
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**From:** BERN  
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**Line Count:** 69  
**Litigation Code IDs:**  
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**Litigation History:**  
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**Message ID:** 7f4d5e90-c288-dd11-92da-001cc4696bcc  
**Office:** ACTION HEW  
**Original Classification:** UNCLASSIFIED  
**Original Handling Restrictions:** n/a  
**Original Previous Classification:** n/a  
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**Page Count:** 2  
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**Previous Handling Restrictions:** n/a  
**Reference:** 78 STATE 138793  
**Retention:** 0  
**Review Action:** RELEASED, APPROVED  
**Review Content Flags:**  
**Review Date:** 29 mar 2005  
**Review Event:**  
**Review Exemptions:** n/a  
**Review Media Identifier:**  
**Review Release Date:** N/A  
**Review Release Event:** n/a  
**Review Transfer Date:**  
**Review Withdrawn Fields:** n/a  
**SAS ID:** 2461379  
**Secure:** OPEN  
**Status:** NATIVE  
**Subject:** FDA ADVISORY - DEFECTIVE INTRA-AORTIC BALLOON PUMPS (RECALL T-098-8)  
**TAGS:** OGEN, EIND, TBIO, XG  
**To:** STATE  
**Type:** TE  
**vdkgvwkey:** odb://SAS/SAS.dbo.SAS\_Docs/7f4d5e90-c288-dd11-92da-001cc4696bcc  
**Review Markings:**  
Sheryl P. Walter  
Declassified/Released  
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**Markings:** Sheryl P. Walter Declassified/Released US Department of State EO Systematic Review 20 Mar 2014